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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,375	10/16/2001	Avi J. Ashkenazi	GNE.2630P1C24	4717

35489 7590 08/02/2005

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,375	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/19/02; 6/9/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: attachment

DETAILED ACTION

The preliminary amendments filed 10/16/2001, 02/20/2002 and 04/19/2002 are acknowledged. The amendments have been entered. The specification has been amended as indicated. Claims 1-57 have been cancelled. Claims 58-70 are currently pending in the application and are addressed herein.

Title and Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. For example, see page 124, line 37 and page 127, line 18. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Applicant is required to delete ALL embedded hyperlinks and/or other forms of browser-executable code. See MPEP § 608.01.

The disclosure is objected to because of the following informalities: the address disclosed for ATCC (e.g., see page 372, lines 34-35) is incorrect, ATCC is now located in Manassas, VA. Additionally, the status of the prior US application 09/918,585 (now abandoned) should be updated (e.g., see preliminary amendment filed 9/3/2002).

Appropriate correction is required.

Biological Deposits

A statement in the specification indicating that the biological deposit ATCC 209616 has been deposited under the provisions of the Budapest Treaty can be found in the specification (see under "Deposit of Material" on page 372 through page 375 of the specification. The statement indicates that under the provisions of the Budapest Treaty, a viable culture of the deposit will be maintained for 30 years form the date of deposit, and that the deposit will be made available by ATCC under the terms of the Budapest Treaty, and subject to an agreement between Genentech, Inc. and ATCC, which assures permanent and unrestricted availability of the progeny of the culture of the deposit to the public upon issuance of the pertinent U.S. patent or upon laying open to the public of any U.S. or foreign patent application, whichever comes first, and assures availability of the progeny to one determined by the U.S. Commissioner of Patents and Trademarks to be entitled thereto according to 35 USC 122 and the Commissioner's rules pursuant thereto (including 37 CFR 1.14 with particular reference to 886 OG 638).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 4/19/2002 and 6/9/2003 are acknowledged. With respect to the IDS submitted 6/9/2003, the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. With respect to the IDS submitted 4/19/2002, the database search results have not been considered because the information on the referred databases is incomplete. In order for the databases referred to be considered, Applicants are required to provide complete information, including such database name, accession number, and publication date.

Specific and Substantial Asserted Utility

It is noted that the instant claims are drawn to an isolated polypeptide (the PRO363 polypeptide) as well as variants/fragments of the polypeptide, etc. The specification discloses that the PRO363 polypeptide was tested in a number of different assays and was found to test positive in, among others, Assay 110: chondrocyte re-differentiation assay (e.g., see Example 126, page 351). The specification asserts using PRO363 in the treatment of bone or cartilage disorders such as arthritic conditions and sports injuries (e.g., see p. 351, lines 19-21). It is well recognized that human articular chondrocytes can be isolated, grown in culture and then injected into an injured area of bone or cartilage for treatment. A common problem with culturing the chondrocytes is that they differentiate into fibroblastic type cells rendering them useless for treatment. Compounds that have the "redifferentiation" activity in this assay prevent the cultured chondrocytes from differentiating into the non-usable fibroblasts. As such, the claimed polypeptide sequences are deemed to have a specific and substantial utility.

Priority

According to the priority statement of 09/03/2002, the claimed subject matter defined in the instant application is supported by parent application serial nos. 09/918585, PCT/US00/04341, 09/380138, PCT/US99/05028, and 60/078910. Based on the information given by applicant and an inspection of the patent applications, the examiner has concluded that the subject matter defined in this application is supported by the disclosure in application serial no. PCT/US00/04341, filed 18 February 2000, but is not supported by any of the earlier

applications because no utility for the claimed polypeptide, PRO363, is disclosed in the earlier applications. The results of the chondrocyte redifferentiation assay are first reported in PCT/US00/04341. Under 35 U.S.C. 120, a claim in a U.S. application is entitled to the benefit of the filing date of an earlier filed U.S. application if the subject matter of the claim is disclosed in the manner provided by 35 U.S.C. 112, first paragraph, in the earlier filed application. See MPEP 201.11. Since the applications prior to PCT/US00/04341 do not disclose a specific and substantial utility for the PRO363 polypeptide, they are not enabling.

Accordingly, the subject matter defined in claims 58-70 have an effective filing date of February 18, 2000.

Should the Applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page numbers of any parent application filed prior to February 18, 2000 that specifically supports the particular claim limitations for all the pending claims which applicant considers to have been in possession of and fully enabled prior to February 18, 2000.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58-62, 69 and 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to isolated polypeptides wherein the polypeptides have at least 80%, 85%, 90%, 95% or 99% sequence identity with the sequence disclosed as SEQ ID NO: 59 (PRO363). The claims do not require that the polypeptides possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of molecules that is defined by sequence identity only.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. As stated above, it is not even clear what region of the protein has the disclosed activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at

page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 59 but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 58-62, 69 and 70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated polypeptide of SEQ ID NO: 59, does not reasonably provide enablement for a polynucleotide encoding a polypeptide not identical to SEQ ID NO: 59, as well as a non-isolated cell comprising the polynucleotide. The specification does

not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are drawn to a polypeptides having at least 80% identity to SEQ ID NO: 59 (PRO363) or the extracellular domain thereof, and chimeric molecules comprising PRO363. It is noted that there are no functional limitations in the claims. Applicants have taught the polypeptide of SEQ ID NO: 59, and have identified specific amino acids as the signal sequence (amino acids 1-16) and the transmembrane domain (amino acids 232-251) (See Figure 24). The specification discloses that "PRO363" was shown to have several distinct functions including: causing chondrocyte re-differentiation (Assay 110, Example 126, p. 351), increasing proliferation of rat utricular supporting cells (Assay 54, Example 116, p. 347), and increasing proliferation of kidney cells (Assay 92, Example 124, p. 350) but does not indicate whether the entire protein or a specific region of PRO363 was used in the experiments. Therefore, it is not clear which specific amino acids of PRO363 are critical for each of the disclosed activities. Without a clear indication of the amino acids that are critical for each function of PRO363, one of skill in the art would not know which amino acids could be changed such that the variant

protein still had the desired function. Additionally, the claims encompass variants of PRO363 that are inoperative and which the skilled artisan would not know how to use.

Additionally, the art recognizes that a high degree of structural homology may not result in functional homology. **Witkowski** et al. (Biochemistry 38:11643-11650, 1999) teaches that one amino acid substitution transforms a β-ketoacyl synthase into a malonyl decarboxylase and completely eliminates β-ketoacyl synthase activity. **Seffernick** et al. (J. Bacteriol. 183(8):2405-2410, 2001) teaches that two naturally occurring Pseudomonas enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Therefore, the claimed genera of polynucleotides have the potentiality of encoding proteins of many different functions.

Furthermore, there are no working examples demonstrating that polypeptides less than 100% identical to the polypeptide SEQ ID NO: 59 have any of the disclosed functions. The skilled artisan would not know how to use non-identical polypeptides on the basis of teachings in the prior art or specification unless they possessed a function disclosed in the instant specification. The specification does not provide guidance for using polypeptides related to (*i.e.*, 80%-99% identity) but not identical to SEQ ID NO: 59 which do not have a specific disclosed activity.

For these reasons, which include the complexity and unpredictability of the nature of the invention and art in terms of the diversity of the variant proteins encompassed by the claims, and lack of knowledge about function(s) of the encompassed polypeptides structurally related but not identical to SEQ ID NO:59, the limited working examples demonstrating function of PRO363 polypeptide, the lack of direction or guidance for using polypeptides that are not identical to SEQ

ID NO:59, and the breadth of the claims for structure without function, it would require undue experimentation to use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 58-70 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0055139 A1 (HOLTZMAN et al., published May 9, 2002 with priority to 09/312,359, filed May 14, 1999).

HOLTZMAN teaches a polypeptide (human A236 protein) that is 100% identical to SEQ ID NO: 59 (See attached sequence alignment), (e.g., see HOLTZMAN paragraph [0129] describing Figure 23, SEQ ID NO: 23 and SEQ ID NO: 24). Since the polypeptide taught by HOLTZMAN is 100% identical to SEQ ID NO: 59, it would necessarily encode the extracellular domain of SEQ ID NO: 59. HOLTZMAN also teaches the mature form of the A236 protein and indicates that the mature form results from cleavage of the signal peptide (e.g., see paragraphs [0302], [0303] and [0314]). Therefore, the mature form of the A236 protein lacks its associated signal peptide, and the mature form of the A236 protein would necessarily be a polypeptide comprising the extracellular domain of SEQ ID NO: 59 lacking its associated signal peptide. HOLTZMAN also teaches that the A236 protein can be a chimeric

polypeptide comprising a polypeptide fused to a heterologous polypeptide (e.g., see paragraph [0595]). Specifically, HOLTZMAN teaches that the chimeric polypeptide comprises a GST sequence (i.e., an epitope tag) (e.g., see paragraph 0597]) or an immunoglobulin constant region (i.e., an Fc region of an immunoglobulin).

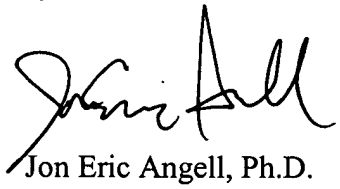
Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon Eric Angell, Ph.D.
Art unit 1635

GenCore version 5.1.6
OM protein - protein search, using sw model
Run on: May 5, 2005, 08:03:49 ; Search time 164 Seconds
(without alignments)
879.644 Million cell updates/sec

Title: US-09-978-375A-59
Perfect score: 1908
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Scoring table: BLOSUM62
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Searched: 2105692 seqs, 386760381 residues
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Maximum Match 100%
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2: geneseqp1990s:*
3: geneseqp2000s:*
4: geneseqp2001s:*
5: geneseqp2002s:*
6: geneseqp2003as:*
7: geneseqp2003bs:*
8: geneseqp2004s:*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

No.	Score	Match Length	DB	ID	Description

RESULT 1
ID AAY41692 standard; protein; 373 AA.
DE Human PRO 363 protein sequence.
PN WO9946281-A2.
PD 16-SEP-1999.
PA (GETH.) GENENTECH INC.
Query Match 100.0%; Score 1908; DB 2; Length 373;
Best Local Similarity 100.0%; Pred. No. 3.7e-145;
RESULT 2
ID AAB33430 standard; protein; 373 AA.
DE Human PRO363 protein UNQ318 SEQ ID NO:87.
PN WO200053758-A2.
PD 14-SEP-2000.
PA (GETH) GENENTECH INC.
Query Match 100.0%; Score 1908; DB 3; Length 373;
Best Local Similarity 100.0%; Pred. No. 3.7e-145;
RESULT 3
ID AAB44248 standard; protein; 373 AA.
DE Human PRO363 (UNQ318) protein sequence SEQ ID NO:59.
PN WO200053756-A2.
PD 14-SEP-2000.
PA (GETH) GENENTECH INC.
Query Match 100.0%; Score 1908; DB 3; Length 373;
Best Local Similarity 100.0%; Pred. No. 3.7e-145;
RESULT 4
ID AAU12365 standard; protein; 373 AA.
DE Human PRO363 polypeptide sequence.
PN WO200140466-A2.
PD 07-JUN-2001.
PA (GETH) GENENTECH INC.
Query Match 100.0%; Score 1908; DB 4; Length 373;
Best Local Similarity 100.0%; Pred. No. 3.7e-145;
RESULT 5
ID AAB48108 standard; protein; 373 AA.
DE Human A236 polypeptide.
PN WO200069885-A2.
PD 23-NOV-2000.
PA (MILL-) MILLENNIUM PHARM INC.
Query Match 100.0%; Score 1908; DB 4; Length 373;
Best Local Similarity 100.0%; Pred. No. 3.7e-145;
RESULT 6
ID AAB65293 standard; protein; 373 AA.
DE Human PRO363 protein sequence SEQ ID NO:503.
PN WO200073454-A1.
PD 07-DEC-2000.
PA (GETH) GENENTECH INC.
Query Match 100.0%; Score 1908; DB 4; Length 373;
Best Local Similarity 100.0%; Pred. No. 3.7e-145;
RESULT 7
ID AAU83656 standard; protein; 373 AA.
DE Human PRO protein, Seq ID No 130.
PN WO200208288-A2.
PD 31-JAN-2002.
PA (GETH) GENENTECH INC.
Query Match 100.0%; Score 1908; DB 5; Length 373;
Best Local Similarity 100.0%; Pred. No. 3.7e-145;
RESULT 8
ID ABB84848 standard; protein; 373 AA.
DE Human PRO363 protein sequence SEQ ID NO:64.
PN WO200200690-A2.
PD 03-JAN-2002.
PA (GETH) GENENTECH INC.
Query Match 100.0%; Score 1908; DB 5; Length 373;
Best Local Similarity 100.0%; Pred. No. 3.7e-145;
RESULT 9
ID AAE26448 standard; protein; 373 AA.
DE Human A236 protein.
PN US2002055139-A1.
PD 09-MAY-2002.
PA (HOLT/) HOLTZMAN D A.
PA (SHAR/) SHARP J D.
PA (LEIB/) LEIBY K R.
PA (BOSS/) BOSSONE S.
PA (PANY/) PAN Y.
PA (BARN/) BARNES T M.
PA (FRAS/) FRASER C C.
PA (WRIG/) WRIGHTON N.
PA (MYER/) MYERS P S.
PA (KING/) KINGSBURY G.
Query Match 100.0%; Score 1908; DB 5; Length 373;
Best Local Similarity 100.0%; Pred. No. 3.7e-145;
RESULT 10
ID ABB95454 standard; protein; 373 AA.
DE Human angiogenesis related protein PRO363 SEQ ID NO: 64.
PN WO200208284-A2.
PD 31-JAN-2002.
PA (GETH) GENENTECH INC.
PA (BAKE/) BAKER K P.
PA (FERR/) FERRARA N.
PA (GERB/) GERBER H.
PA (GERR/) GERRITSEN M E.
PA (GODD/) GODDARD A.
PA (GODO/) GODOWSKI P J.
PA (GURN/) GURNEY A L.
PA (HILL/) HILLAN K J.
PA (MARS/) MARSTERS S A.
PA (PANJ/) PAN J.
PA (PAON/) PAONI N F.
PA (STEP/) STEPHAN J F.
PA (WATA/) WATANABE C K.
PA (WILL/) WILLIAMS P M.
PA (WOOD/) WOOD W I.
Query Match 100.0%; Score 1908; DB 5; Length 373;
Best Local Similarity 100.0%; Pred. No. 3.7e-145;
RESULT 11
ID ABU58108 standard; protein; 373 AA.
DE Human PRO polypeptide #140.
PN US2003027163-A1.
PD 06-FEB-2003.
Query Match 100.0%; Score 1908; DB 6; Length 373;
Best Local Similarity 100.0%; Pred. No. 3.7e-145;
RESULT 12
ID ABU59186 standard; protein; 373 AA.
DE Novel human secreted or transmembrane protein PRO363.
PN US2002132252-A1.